

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING	\$
PHARMACY, INC. PRODUCTS	\$
LIABILITY LITIGATION	\$

§ MDL No. 13-2419

§ Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO: §

## All Cases Against the Saint Thomas Entities §

**SAINT THOMAS ENTITIES' OBJECTIONS TO ORDER DENYING MOTION TO  
DISSOLVE PROTECTIVE ORDERS AND LIFT STAYS AND REQUEST FOR  
RULING ON OMNIBUS MOTION**

The Saint Thomas Entities<sup>1</sup> file these objections to the Court’s Electronic Order (Docket #2861) (“Order”) denying *Defendants Saint Thomas Health, Saint Thomas Network, and St. Thomas Hospital’s Motion to Dissolve Protective Orders and Lift Stays Barring Certain Depositions* (Docket #2860) (“Motion to Dissolve”). The Saint Thomas Entities further request that the Court rule on the outstanding portions of *Defendants Saint Thomas Health, Saint Thomas Network, and St. Thomas Hospital’s Motion for Relief as to Proposed Bellwether Trials* (Docket #2785) (“Motion for Relief”) and brief in support (Docket #2786) (“Omnibus Memo”) for the following reasons:

## PRELIMINARY STATEMENT

The Saint Thomas Entities have recently filed two materially related motions addressing the risks and concerns inherent in allowing the civil trials to precede the criminal trials of the NECC Insider Defendants. First, they filed an Omnibus Motion seeking various types of relief as to the proposed trial dates for the Bellwether Plaintiffs. The Court “allowed” that motion, but only to the extent it asked for a deferral of the first Bellwether Trial, and set the *Wray* case for trial on

<sup>1</sup> Saint Thomas West Hospital, formerly known as St. Thomas Hospital (“Hospital”), Saint Thomas Network (“Network”), and Saint Thomas Health (“Health”) (collectively, the “Saint Thomas Entities”). The Saint Thomas Entities will continue to use the terms they defined in their Omnibus Motion.

August 22, 2016. (Docket #2828). The Court did not rule on the other requests for relief, including clarification of the procedure and timing for remand to the Tennessee federal court under 28 U.S.C. § 1407 and deferral of any civil trials until after the completion of at least the evidentiary portions of the criminal trial against the NECC Insiders.<sup>2</sup>

In light of the fact that the August 22 setting predates the September 8 criminal trial (by only one week), the Saint Thomas Entities sought to dissolve the protective orders and lift the stays barring certain depositions of the NECC Insiders, Joseph Connolly, and John Notarianni (“Government Witnesses”), and the U.S. Food and Drug Administration (“FDA”), so that those depositions could go forward in time to permit crucial discovery as necessary to explain what actually happened to the civil jury. As the Saint Thomas Entities pointed out, this discovery is relevant to the Bellwether Plaintiffs’ case-in-chief—such as causation—as well as to the Saint Thomas Entities’ comparative fault defenses. The Court denied the Motion to Dissolve without waiting for a response from the PSC. *See* Order (Docket #2861).

The combination of rulings puts the Saint Thomas Entities in the untenable and unfairly prejudicial position of being put to trial without the proof necessary to defend themselves. As they have previously demonstrated, the PSC has no incentive to develop the evidence of any wrongdoing by NECC and the NECC Insiders or the FDA.<sup>3</sup> To the contrary, now that NECC and the Insiders have settled, the PSC’s strong preference is to downplay the conduct of the third parties so as to maximize the liability against the Saint Thomas Entities—even though these defendants played absolutely no role in the contamination or procurement of methylprednisolone acetate

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<sup>2</sup> The “NECC Insiders” are entities and individuals affiliated with NECC, including Barry and Lisa Cadden; Doug, Carla, and Greg Conigliaro; Glenn Chin; Alaunus Pharmaceutical, LLC; Ameridose, LLC; GDC Properties Management, Inc.; Medical Sales Management, Inc.; and Medical Sales Management, SW, Inc. Not all NECC Insiders are subject to the criminal proceedings, but the managers of the companies listed above are.

<sup>3</sup> In fact, the PSC has moved for a partial summary judgment to eliminate the FDA from the comparative fault question. *See* Docket #2862.

(“MPA”) from NECC or providing epidural steroid injections to any patients. As a result, the Saint Thomas Entities have pursued this critical discovery aggressively for some time now, but have been prevented from obtaining it at each turn. To defend themselves, the Saint Thomas Entities should be allowed to discover and develop the evidence as to how the contamination occurred and who is responsible.

### ARGUMENT

#### **I. The Denial of Discovery From the Culpable Parties Unnecessarily Risks the Saint Thomas Entities’ Ability to Defend Themselves in the Civil Trials**

A district judge may modify or set aside a magistrate’s non-dispositive order only if it is “clearly erroneous or contrary to law.” 28 U.S.C. § 636(b)(1)(A); FED. R. CIV. P. 72(a). The Order should be modified or set aside to permit the Saint Thomas Entities to obtain the critical evidence from the NECC Insiders, Government Witnesses, and FDA. The Saint Thomas Entities have detailed several of the specific items they need from these deponents in order to defend the claims against them. Motion to Dissolve at 5-8.<sup>4</sup> Proof of the following is not purely documentary—it can only come in the form of live testimony from the key witnesses with knowledge:

- NECC failed to properly compound the MPA to eliminate the fungal contamination by, among other things, failing to autoclave the MPA according to the standards of United States Pharmacopeia (“USP”) 797 and NECC’s own written procedures, failing to terminally sterilize the MPA, and failing to conduct final product testing as also required by USP 797, which would have identified the contamination before it reached any patient.
- The fungus that contaminated the MPA entered the cleanroom from gaps in the ceiling grid that were misaligned by Liberty Industries at the time the cleanroom at issue was installed in 2006.
- ARL BioPharma, Inc. failed to perform USP 71 testing on each of the three lots of contaminated MPA.

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<sup>4</sup> In their Motion to Dissolve, the Saint Thomas Entities incorporated by reference their prior briefing: *Opposition to the Invoking Defendants’ Motion for Protective Orders and To Quash Deposition Notices*, Docket #1869 at 5-13, *Response to United States’ Motion for Leave to Intervene and For A Stay of Certain Depositions Pending Resolution of Related Criminal Proceedings*, Docket #2275 at 3-13; and the *Tennessee Clinic Defendants’ Response to FDA’s Motion for Protective Order*, Docket #1881 at 5-9. And they further incorporate that briefing by reference in these objections.

- UniFirst Corporation, the company with sole responsibility for cleaning the walls and ceilings of the cleanroom where the MPA was compounded, failed to devote the time needed to properly clean, and failed to use proper cleaners or technique.

Joe Connolly is necessary to explain how NECC was actually compounding medications compared to what they were telling their customers they were doing. And John Notarianni, the NECC salesman assigned to cover Saint Thomas Outpatient Neurosurgical Center (“STOPNC”), is needed to explain the sales process that was used to provide comfort and assurance to customers that NECC only made and sold the highest quality medications available. This proof is not available from other sources. In addition, the story of how NECC and its marketing wing MSM were run, including how product was actually made, is a key part of the bellwether trials, and only fact witnesses with personal knowledge—the NECC Insiders—can take the stand and provide that sworn testimony. Even if a witness pleads the Fifth Amendment privilege as to all substantive testimony, a jury is entitled to be introduced to the witness, particularly to key witnesses like Barry Cadden. And he should have no defense to testifying about familial relationships, such as his wife, business partner, and fellow pharmacist, Lisa Conigliaro Cadden. Or his brother- and sister-in-law, Greg and Carla Conigliaro. Allowing these parties a blanket protection from any testimony in the civil trials—especially when they no longer have personal liability to the Plaintiffs—was contrary to First Circuit precedent. *See* Motion to Dissolve at 9-13.

The FDA should also be required to provide testimony. The FDA had regulatory oversight over NECC, and can also provide critical, disinterested testimony as to the condition of NECC’s premises when it conducted its inspection in 2012, as well as its testing and findings. *Id.* at 13-14.

The Court’s order denying the Motion to Dissolve provides two reasons, neither of which is sufficient to overcome the Saint Thomas Entities’ showing of their right to relief. First, although the Court acknowledged the criminal trials had been set to begin before the civil trials at the time the protective orders and stays were originally entered, the Court now indicates that “there always

existed the possibility that the order could be reversed.” Order (Docket #2861). The Saint Thomas Entities understood the prior orders only to defer that discovery until a later date, not to preclude it entirely. *See, e.g.*, Docket #2123 at 21 (“The Court realizes that precluding the FDA’s deposition until resolution of the criminal case might mean that the Tennessee Clinic Defendants will be unable to take the deposition of the FDA *prior to the conclusion of common fact discovery* in these cases.” (emphasis added)); Docket #2556 (“The depositions of Joseph Connolly and John Notarianni are *stayed until the conclusion of the first criminal trial at which they testify or further order of the Court.*” (emphasis added)).

Any number of events could have intervened in the last year, such as plea agreements, and the fruits of the criminal trial would be available without risk to any Fifth Amendment rights of the third parties. And the Court’s prior orders contemplated that changed circumstances might necessitate revisiting whether and when depositions of NECC-related individuals and entities, and of the FDA, should occur. *See* Docket #2123 at 15 (“The Court is persuaded that the depositions of the Insider Defendants who are defendants in the criminal case should not go forward *at this time.*” (emphasis added)). It was not clear to the Saint Thomas Entities that they would be trying the civil cases without *any* discovery as to these deponents until the Court set the first Bellwether Trial for August 22—ahead of the criminal trial. And they filed the Motion to Dissolve promptly—within ten days of the order setting that trial.

The second justification for the Order is a suggestion of waiver—that the Saint Thomas Entities should have appealed from the prior orders at the time they were entered in July of 2015 and January 2016, Order (Docket #2861). Although the deferral of this discovery has created challenges for these parties, the full-blown harm was not realized until the first Bellwether Trial was set on April 26, 2016, ahead of the criminal trials. This circumstance was not known—and could only have been speculated—prior to the actual trial setting. And the fact of the trial setting

is a new circumstance that warrants a different consideration. The prior orders merely deferred discovery, while the impact of the trial setting (and refusal to continue it until after the criminal trial) in light of the current discovery prohibitions is that the Court is effectively ruling this evidence to be inadmissible—even though there is no question of its relevance and importance to the case. *See* Docket #2123 at 15-16 (discussing overlap between civil and criminal proceedings). Moreover, as the Court is aware, the Saint Thomas Entities have been extremely judicious in seeking reconsideration or appellate relief.<sup>5</sup> They have diligently developed the case as best they could in light of numerous orders of the Court, some favorable, some not. The Court’s suggestion of waiver may set a dangerous precedent of requiring motions for reconsideration and objections/appeal from every interim order in order to avoid risk.

As the Saint Thomas Entities have demonstrated, they should not be put to trial without the currently inaccessible proof from the criminal proceedings. *See* Motion to Dissolve at 14-18. The Court has a variety of options for affording relief to prevent the unquestionable prejudice to the Saint Thomas Entities. It can and should dissolve the protective orders and lift the stays, defer the civil trials under after the evidence presentation in the criminal trial, and/or remand the cases to their originating courts in Tennessee for trial. *See* Part II. Further, the interests of the Government and the Criminal Defendants can be protected through an “Attorney’s Eyes Only” process that includes limiting review to counsel for the remaining parties and sealing the courtroom. *See* Motion to Dissolve at 3-4 (citing *United States v. Parcels of Land at 78-98 Middlesex St., Lowell*, No. CIV. A. 88-2424-Z, 1989 WL 73301, at \*3 (D. Mass. June 16, 1989), *aff’d*, 903 F.2d 36 (1st Cir. 1990)).

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<sup>5</sup> The Saint Thomas Entities’ co-defendants, Ascension and Ascension Health, filed a motion for certification under Rule 54(b) as to the order dismissing the complaints against those defendants, Docket #1521, but the Saint Thomas Entities have not filed any requests for appellate relief.

## **II. The Court Is Respectfully Requested to Rule on the Outstanding Issues of the Saint Thomas Entities' Omnibus Motion**

Although the Court “allowed” the Saint Thomas Entities’ Omnibus Motion, it granted only a brief respite in the setting of the first Bellwether Trial. The Court did not defer the trial until after the NECC criminal trial, which is definitively set for September 8. Other significant portions of the Omnibus Motion are outstanding, and the Saint Thomas Entities request the Court to rule on those alternatives.

The Court entered its order on April 26, 2016, before the Saint Thomas Entities filed a reply brief in response to the PSC’s brief in opposition to the Omnibus Motion. *See Plaintiffs’ Steering Committee’s Response in Opposition to Saint Thomas Entities’ Motion to Stay Bellwether Trials [sic] [Dkt. No. 2785]* (Docket #2813) (“Opposition”). The following responds to the PSC’s arguments in its Opposition.

In their Omnibus Memo, the Saint Thomas Entities demonstrated that the Bellwether Plaintiffs’ trials the Court had been contemplating setting for summer 2016 should be deferred for a number of reasons, including resolution of the MDL process under 28 U.S.C. §§ 157(b)(5) and 1407, completion of at least the evidentiary portions of the criminal trial against the NECC Insiders, and sufficient opportunity for the parties to complete pretrial proceedings and try the individual cases to completion. The PSC’s response is that these matters have already been decided, it is unlikely that either the NECC Insiders or the National Defendants caused the MPA contamination, the Saint Thomas Entities have everything they need to try the Bellwether cases, and the Tennessee Plaintiffs should not have to wait any longer. None of these reasons overcomes the Saint Thomas Entities’ entitlement to the relief they seek

The trial venue is not settled—the Court specifically indicated that it intends to remand the bellwether cases back to Tennessee, at which point it will entertain a motion to set the trial venue

in Boston.<sup>6</sup> And to suggest that the Saint Thomas Entities “only have a limited interest in seeing the criminal case go forward first”<sup>7</sup> is to fail to read the Omnibus Memo or supporting exhibits. The PSC’s new argument that it would have had difficulty proving the NECC Insiders and National Defendants caused the MPA contamination ignores both its own press releases and the assertions of the government that the criminal trial “will reveal overwhelming evidence of [Barry Cadden and Glenn Chin’s] extreme recklessness and wanton and willful disregard for human life that directly caused [the meningitis victims’] deaths. ... This was not an unfortunate unexplainable tragedy; this was murder.”<sup>8</sup> If the evidence the government has in its possession—that has thus far been denied to the Saint Thomas Entities—is sufficient to establish that NECC Insiders committed such egregious crimes as to fungal meningitis victims, then the juries in the civil cases should hear that same evidence when considering the fault of NECC, as well as the settling parties who worked with NECC, and any liability of the healthcare defendants. A brief delay will allow the civil defendants this access without corresponding harm to the Bellwether Plaintiffs.

**A. Resolution of the Procedural Hurdles to Trying the Cases Here Will Take Time**

The Saint Thomas Entities laid out the procedure and timeline needed for the Court to be in a position to try the Bellwether Plaintiffs’ cases—a process that will require involvement of the JPML, as well as the Clerk of this Court and the parties to designate and create a record to send to the Tennessee court once remanded. Omnibus Memo at 2-3 (citing October 7, 2015 Order (Docket #2309)). And the ultimate issue of trial venue has to be addressed. *Id.*

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<sup>6</sup> Docket #2309 at 25.

<sup>7</sup> See Opposition at 7.

<sup>8</sup> See *Government's Opposition to Defendants' Motion to Dismiss Count 1 (RICO) and Count 2 (RICO Conspiracy), and to Strike Murder Racketeering Acts From Count 1*, NECC Criminal Case 1:14-cr-10363-RGS (Docket #456) at p. 15-16.



In its Opposition, the PSC focuses solely on jurisdiction and venue under § 157(b)(5), asserting that the Court has already ruled on the question and so should not engender any further delay. Opposition at 1-2. But the order says no such thing. In fact, the Court made clear that the question was still to be briefed and decided after an appropriate motion is filed upon remand:

*I will then consider the motion and hold a hearing to assess whether it is ultimately appropriate to transfer the cases to this district for trial. If it is, I will issue an order to that effect and promptly schedule a pretrial conference.*

Docket #2309 at 25 (emphasis added). The PSC is correct that the Court can expedite briefing process on the § 157(b)(5) issues, but doing so would only address one of the logistical issues inherent in the process outlined by the Court. The PSC presumably has no response to the other timing and logistical matters presented by procedural posture of this MDL. Omnibus Memo at 2-3. But the Court should take them into account when considering any trial settings.

**B. The Public and Private Interests at Stake Overwhelmingly Favor a Brief Delay**

The PSC is correct that this case is in a unique position. Opposition at 4-5. Here, unlike many of the cases cited by both parties, it is not the criminal defendant who seeks a stay to protect his or her Fifth Amendment privilege against self-incrimination. The criminal defendants were previously provided a blanket stay from any discovery because of their criminal trial. The Court has already afforded them the “extraordinary” relief that the reported cases make clear should not be presumed, but can only be granted based on showing “a clear case of hardship.” Opposition at 2 (collecting cases); *see also* Docket #2123 at 14-16. It is as a result of that relief that the Saint Thomas Entities are suffering substantial hardship because they are prevented from obtaining the facts they need to defend the claims made against them by demonstrating the culpability of the NECC insiders and others.

**1. The Saint Thomas Entities Should Not Be Put to Trial Without the Proof They Need to Defend Themselves**

Both parties have pointed out that the decision whether to sequence the criminal trial first involves a balancing of the competing interests. The Saint Thomas Entities have previously detailed the substantial and unjustifiable harm that will be occasioned upon them if they are required to defend themselves before a jury without the NECC evidence. *See* Omnibus Memo at 11-14. The PSC's response is merely that "Defendants have the information they need" from "the record compiled." Opposition at 3. The PSC's subjective view of what is "necessary" for the Saint Thomas Entities to defend themselves at trial is both inaccurate and irrelevant. The PSC presumably relies upon the documents NECC and the Insider Defendants selectively produced during the mediation program very early on in the litigation. *See* Omnibus Memo at 15. By contrast, the government has indicated that it has voluminous information to prove serious criminal conduct beyond a reasonable doubt. *See* Omnibus Memo at 11-14. And there is no question that the Saint Thomas Entities do *not* have access to the government's sources.

Weighed against this demonstrated harm is the PSC's assertion that "[f]urther delays to await the criminal prosecution are simply unnecessary and will prejudice Plaintiffs." Opposition at 3. Notably, the PSC fails to articulate any specific prejudice that these Bellwether Plaintiffs would suffer from a very brief delay—other than the mere fact of delay—presumably because they cannot. *See In re Adelpia Commc'ns Sec. Litig.*, 2003 WL 22358819, at \*4 (E.D. Pa. May 13, 2003) ("[C]ourts may insist that [the party opposing the stay] establish more prejudice than simply a delay in his right to expeditiously pursue his claim."). Here, the government's case against the criminal defendants is definitively set for September 8, and allowing that case to go forward first

will permit the Saint Thomas Entities to avoid entirely the irreparable harm they would suffer from being forced to try these cases without proof of the true facts.<sup>9</sup>

The PSC argues that the Saint Thomas Entities' position is "unsupported and unprecedented." Opposition at 5. Yet, one of the cases cited by the PSC does precisely what the Saint Thomas Entities are requesting. In *Trustees of the Plumbers and Pipefitters National Pension Fund v. Transworld Mech., Inc.*, 886 F. Supp. 1134, 1140-41 (S.D.N.Y. 1995), the court stayed civil proceedings against the individuals who were facing parallel criminal prosecution for reasons similar to the ones advanced here: (i) the proceedings were substantially overlapping and risked compromise of the individual defendants' Fifth Amendment rights; (ii) evidence gathered in the criminal prosecution would be available for the civil trial; (iii) the criminal trial was set in six months; (iv) "resolution of the criminal case may increase the possibility of settlement due to the high standard of proof required in a criminal prosecution;" and (v) the constitutional rights at stake and judicial efficiency concerns more than offset any harm that would be occasioned by a brief delay of the civil trial. Having made that decision, the court then considered whether to stay the case against the corporate defendants who were not parties to the criminal trial. *Id.* at 1141. It did so primarily because the corporations were controlled by the individual defendants. *Id.* Its analysis is instructive for this case as well: "[B]ecause of the importance of the[] testimony [of the individual defendants], a partial stay could lead to duplicative discovery efforts," and "the evidence garnered in the criminal trial could reduce the scope of discovery in the civil case," the court stayed the civil proceedings against the corporate defendants as well pending resolution of

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<sup>9</sup> Contrary to the PSC's suggestion, Opposition at 7, the U.S. government has already weighed in on the matter and received extraordinary relief in the form of a blanket stay as to the criminal defendants and other witnesses for the criminal trial. Docket ## 2123, 2354, 2403, 2556. The issue here is whether it is fair for the civil defendants to be forced to go forward without the benefit of the proof from the criminal defendants, which is unquestionably relevant—*see* Omnibus Memo at 4-6 (discussion of overlap between civil and criminal cases)—and also critically important to the Saint Thomas Entities, whose primary defense will be that they did not cause the Bellwether Plaintiffs' injuries.

the criminal proceedings. *Id.*; *see also* Motion to Dissolve at 15-18 (collecting cases). As all of these courts have acknowledged, the court has the “inherent *discretionary* authority to stay cases to manage its docket in the interest of justice and efficiency.” *Arden Way Assocs. v. Boesky*, 660 F. Supp. 1494, 1496 (S.D.N.Y. 1987) (emphasis in original) (citation and quotation marks omitted); *see also Landis v. N. Am.*, 299 U.S. 248, 254-55 (1963). Exercise of that discretion is amply warranted here.

The PSC cites several other cases that it claims support its position that the civil cases should go first. *See* Opposition at 4-5 & nn.12-14. Those cases do not support its assertion for several reasons. First, the Court has already granted a blanket stay as to the criminal defendants and so has already made the determinations necessary to support that relief, including findings that the cases substantially overlap and the defendants’ intentions to invoke the Fifth Amendment provides a sufficient basis for staying all discovery as to them. Docket #2123 at 15-16.

Second, *SEC v. K2 Unlimited, Inc.*, 15 F. Supp. 3d 158, 161 (D. Mass 2014),<sup>10</sup> *SEC v. Dresser Indus., Inc.*, 628 F.2d 1368, 1375-76 (D.C Cir. 1980), and *SEC v. Caramadre*, 117 F. Supp. 2d 217 (D.R.I. 2010), involved parallel civil proceedings brought by the SEC under its statutory enforcement powers. The public’s interest in allowing the SEC to fully pursue the regulatory action is very different from a private plaintiff’s interest in recovering individual relief: “Effective enforcement of the securities laws requires that the SEC and [Department of] Justice be able to investigate possible violations simultaneously.” *Dresser Indus.*, 628 F.2d at 1377.

Third, *Microfinancial*, *Caramande*, *Dresser*, and *Sterling Nat’l Bank v. A-1 Hotels Int’l, Inc.*, 175 F. Supp. 2d 573, 578 (S.D.N.Y. 2001), all involved situations where no indictments had been issued. As those courts recognized, the case for a stay becomes much more compelling after

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<sup>10</sup> In *K2*, the court also found that the criminal and civil proceedings did not overlap, *SEC v. K2 Unlimited, Inc.*, 15 F. Supp. 3d 158, 161 (D. Mass 2014), while this Court has already made a contrary finding and granted extraordinary relief to protect the government witnesses in this case. Docket #2123 at 15-16.

indictment. *See Caramandre*, 717 F. Supp. 2d at 221 (“[A]n unindicted defendant who argues that going forward with a civil proceeding will jeopardize his Fifth Amendment rights usually presents a much less robust case for [the] extraordinary relief” of staying the matter.” (quoting *Microfinancial*, 835 F.3d at 79)); *see also In re Par Pharm., Inc. Sec. Litig.*, 133 F.R.D. 12, 13 (S.D.N.Y. 1990) (“The weight of authority in this Circuit indicates that *courts will stay a civil proceeding when the criminal investigation has ripened into an indictment.*” (emphasis added) (citation omitted)); *cf. Brock v. Tolkow*, 109 F.R.D. 116, 121 (E.D.N.Y. 1985) (“[A] stay of discovery does not mean that enforcement of the public interests at stake in the civil case will be indefinitely deferred. For one thing, a criminal prosecution serves to enforce those same interests.”). In this case, multiple indictments have issued, and the criminal case is set for trial in only a few months. Under similar circumstances, courts have found that a brief delay of the civil trial is warranted. *See Transworld Mech., Inc.*, 886 F. Supp. at 1140-41 (six months).

Fourth, these cases largely involved stays of discovery—*i.e.*, at an early stage of the litigation—and the courts often expressly indicated a willingness to revisit the issue. *E.g.*, *Digital Equip. Corp. v. Currie Enters.*, 142 F.R.D. 8, 14-15 & n.13 (D. Mass. 1991). Here, the case is being positioned for trial, and the considerations for stay need to be weighed differently. *See, e.g.*, *Gaither ex rel. Gaither v. D.C.*, No. Civ. A 03-1458CKK, 2005 WL 3272130, at \*4 (D.D.C. Dec. 2, 2005) (“In its own way, the criminal trial itself—by placing a wide range of testimony under oath—will actually preserve testimony and prevent memories from clouding, thereby obviating or alleviating the central concerns of Plaintiff.”).

## **2. The PSC Is Using the Lack of Access Against the Saint Thomas Entities**

The PSC protests that it is not defending the criminal defendants’ conduct, Opposition at 5, but that is exactly what it is doing—trying to deflect the blame from the actual wrongdoers to the Saint Thomas Entities. The example of expert Laura Thoma is a good one. *See Omnibus*

Memo at 9-10. In this passage, the PSC defended NECC's use of a 15-minute autoclave cycle:

Q: Can you answer my question? Is it your opinion that USP 797 requires autoclaving for 20 minutes at 121 degrees centigrade? Was that your opinion? ... [witness reads USP 797]

A: "To achieve sterility, all materials are exposed to steam at 121 under one -- under a pressure of about one atmosphere of 15 PSI for the duration verified by testing to achieve sterility of the items, which is usually 20 to 60 minutes for [CSPs]."

Q. Okay. So wait a second here. I don't see that where it says 20 minutes is required at 121 degrees. Is that your reading of that?

A. It said usually.

Q: It says usually. Does it say--

A. So it's going to be 20 minimum, so 15, 20. So --

Q. Fifteen could be okay sometimes?

A. *Not for what they were trying to do.*

Q. Fifteen minutes can be okay under certain circumstances, correct?

A. Could be. Does that make you happy now?

Docket #2786-3 at 226:22-228:9 (emphasis added). The PSC was clearly trying to eliminate NECC's improper autoclaving as a cause of the contamination. There can be no other explanation for this aggressive questioning of Ms. Thoma.

Another example is the expert report of Robert Guardino, the PSC's new expert, who opines that he has "seen no evidence that *definitively establishes* when, how or where the contamination of NECC's MPA product occurred. Given the passage of time and the lack of empirical evidence required to draw such a conclusion, *it may never be known* how and when the contamination occurred." Docket #2786-1 at 3 (emphasis added). This report stands in stark contrast to the PSC's prior expert testimony used to defeat Liberty Industries' motion for summary judgment. *See* Docket #1610-1 ¶ 33. The PSC does not even attempt to explain this contradiction.

The PSC's defense of its "about-face" posture as to the wrongdoing of the NECC and National Defendants, Opposition at 6, is not persuasive. Its suggestion that it would have been unable to prove this wrongdoing, *id.*, is remarkable, considering both the position of the U.S. Department of Justice and the PSC's own press releases. While the Saint Thomas Entities have little proof of the specifics due to their inability to access the documents and witnesses who are the only source of those facts, what is available appears to bear out the government's position that it has "overwhelming evidence" of egregious criminal conduct "that directly caused the deaths" of the meningitis victims. *U.S. v. Cadden*, No. 1:14-cr-10363-RGS [Docket #456] at 15-16. And as the PSC promised in its prior pleadings and press statements, there is much reason to believe that the National Defendants are likewise culpable in the contamination. *See* Docket 2786-2; *see also* Omnibus Memo at 10-11 & n.20. Considering just the emails between NECC and UniFirst regarding the repeatedly observed "fungal blooms" that were attached to the government's indictment, there appears to be a great deal more on that front. The considerable and concerning smoke that supports the culpability of the NECC and National Defendants shows that the Saint Thomas Entities should not have to rely on the PSC's claim that there is nothing more.

The Saint Thomas Entities have not conceded that they have sufficient information by producing expert reports. To the contrary, defense experts and counsel alike have experienced considerable frustration with their inability to obtain confirmation of many of the critical facts on causation. They should be allowed to discover and analyze the evidence that will undoubtedly be available to them after the criminal trial is concluded.

The PSC also claims that the Saint Thomas Entities have misled the Court about the payments made to the tort claimants from the Tort Trust Fund. *See* Opposition at 6 n.18. This attempt to cast aspersions on counsel is particularly troubling, when considering that the undersigned sent the PSC an email after the April status conference where the PSC clarified that

payments had not yet been made. Counsel explained the basis of the misunderstanding—from certain statements made by the Post-Confirmation Officer and PSC at an earlier status conference—and informed the PSC that the Saint Thomas Entities would correct that misstatement in their reply. The PSC ignored this attempt to set the record straight. In any event, the PSC also indicated an expectation that the lien issues should be resolved “in the next 2-3 weeks.” And at the May 2016 status conference, the PSC anticipated that the first payments should go out in early July. Those payments from the actual wrongdoers will significantly offset any claimed prejudice from a brief delay of the civil trials against the Saint Thomas Entities.

### **3. The Short Stay Is Sought so That Justice Can Be Done**

The PSC next complains that the Saint Thomas Entities have previously sought stays or more time for discovery, but does not accuse these defendants of dilatory tactics. Opposition at 8-9. They would have no basis for any such accusation. The history of this case more than justifies each of the listed requests, the first of which was filed soon after the Saint Thomas Entities first appeared in the MDL to set aside an aggressive case-management order obtained by the PSC *before* the healthcare providers that it affected had made their appearances. *See* Docket #457. As the Court is aware, the Saint Thomas Entities have worked hard to move this litigation toward a bilateral and representative bellwether process and develop these cases for trial, including fully participating in discovery with the PSC. And they have at the same time diligently pursued discovery from the wrongdoers in this case, repeatedly demonstrating how necessary this proof is to their defense of these cases at trial. *See* Docket ##2275, 2304, 2368.

There is also no basis for the PSC’s characterization of the requested stay as “indefinite.” Opposition at 9. The Saint Thomas Entities seek a stay just until the evidence as to the role of the NECC Defendants is available from the criminal trial. As indicated in their Omnibus Memo at 6-7, the Saint Thomas Entities will be prepared to try the bellwether cases shortly after the



government completes its case-in-chief (assuming that the record will be made available at that time). That trial will commence September 8, so the stay would delay the bellwether trials only briefly, and the PSC has not shown how any of the Bellwether Plaintiffs would be prejudiced by that short duration. Conversely, the Saint Thomas Entities have demonstrated that they will be gravely prejudiced by being forced to trial without access to the sources of the government's proof.

**C. Venue for the Bellwether Trials Should Be in Tennessee**

The Saint Thomas Entities' last request for relief in the Omnibus Memo was for the bellwether trials to be tried in Nashville, where they were all originally filed, rather than Boston. Omnibus Memo at 19-20. The PSC's response is again that the Court has already decided the matter. Opposition at 9-10. But, the Court made clear that the question was still to be briefed and decided. *See* part I above. Although the Court suggested that a motion for trial settings in Boston would likely be successful, that leaning was based on some assumptions that the Saint Thomas Entities respectfully suggest should warrant further consideration. *See* Omnibus Memo at 19-20. Considering all the relevant factors, the Court should remand these cases to Tennessee for trial.

**CONCLUSION AND PRAYER**

For these reasons and those set forth in their Omnibus Motion, the Saint Thomas Entities request that the Court grant the relief requested in the Omnibus Motion.

Dated May 23, 2016

SAINT THOMAS WEST HOSPITAL,  
FORMERLY KNOWN AS ST. THOMAS  
HOSPITAL, SAINT THOMAS  
NETWORK, AND SAINT THOMAS  
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**CERTIFICATE OF SERVICE**

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 23d day of May, 2016.

/s/ Sarah P. Kelly  
SARAH P. KELLY